Naval Health Research Center Detachment
(Environmental Health Effects Laboratory)

TOXICOLOGICAL RISK ASSESSMENT OF A NICKEL COMPOUND FOUND ON THE SURFACES OF REPLACEMENT HYPERSTRETCH NEOPRENE (CWU-83/P) NECK AND WRIST SEALS FOR A COLD WATER SUBMERSION SURVIVAL SUIT

EHEL-03-09

December 2001

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Abstract:

Naval Health Research Center/Toxicology was requested to provide comment and endorse an action plan developed by Naval Air Warfare Center Aeronautics Division (NAWCAD) to remove surface nickel from hyperstretch neoprene (CWU-83/P) neck and wrist seals used in cold water submersion survival suits. The nickel compound present on the surface of the seals is most likely nickeldialkyldithiocarbamate which is a common chemical additive used to prevent photoxidation and breakdown of rubber materials. There is no data on the chronic toxicity or carcinogenicity of nickeldialkyldithiocarbamates. The conservative approach for estimating the toxicological risk of nickeldialkyldithiocarbamate exposure to humans is to assume that these compounds have the same toxic properties as soluble nickel compounds. Lifetime average daily dose (LADD) estimates for persons wearing cold water survival suits were calculated using conservative exposure assumptions. Our calculations suggest that the average surface concentrations of Ni present on Hyperstretch neoprene seals do not pose a significant noncancer toxicological risk for humans. It is possible that a person could be exposed to nickeldialkyldithiocarbamate by hand-to-mouth transfer or by inhalation of airborne neoprene seal particles. However, it was assumed that the potential for oral and inhalation exposure to Ni from exposure to neoprene seals is most likely negligible. Dermal contact with Ni-containing materials may cause allergic skin sensitization and contact dermatitis in certain individuals; the surface concentration of Ni that elicits allergic contact dermatitis reactions in humans has not been determined. Acetone at a concentration of 70-75% should be used to wipe excess nickeldialkyldithiocarbamate from the surface of the neoprene seals at least 10 minutes prior to issue. Seals do not need to be cleaned except when prior to issue. Acetone is a solvent for dissolving rubber and frequent cleaning of the seals with acetone may cause rapid degradation of neoprene rubber over time. Persons involved in the cleaning of the neoprene seals should wear a NIOSH-approved respirator with an organic vapor cartridge.

Background:

On 20 July, 2001, Wendy L. Todd of NAWCAD (Naval Air Warfare Center Aeronautics Division) requested that Naval Health Research Center/Toxicology review and provide endorsement of the attached Draft Memorandum for Record dated 19 July, 2001. The intent of Ms. Todd's Draft Memorandum is: a) to document identification of a fine green film found on stored wrist and neck Hyperstretch Neoprene (CWU-83/P) seals; b) speculate as to the toxic risk posed by the material; and c) outline a plan for removing the green film from the seals. The wrist and neck seals are replacements for wrist and neck seals for Multifabs Survival cold water immersion survival suit. These suits are worn by nonmilitary personnel during transfer flights from ship to ship or shore to ship by helicopter. They are not for routine use by military personnel. The suits are taken out of storage and issued to the passenger and returned to storage after the passenger returns to the issue point.

Samples of the green film were taken from replacement seals that were in storage. Analyses of the green material by NAWCAD chemists found that the film contained mainly nickel and sulfur. Samples of the green material were sent to the McCrone Group (Chicago IL) for further analyses. The McCrone Group concluded that the chemical spectra of the crystals "…matched that of nickeldialkyldithiocarbamate" [ref(b)]. Nickeldialkyldithiocarbamate is commonly added to rubber materials to prevent photoxidation and breakdown of rubber materials. Ms. Todd tried to confirm that the seal manufacturers did incorporate nickeldialkyldithiocarbamate in the seals. However, the manufacturers would not provide information on the chemical composition of the wrist and neck seals because they consider the information to be proprietary. The manufacture is located in Great Britain and is not required by U.S. regulations to reveal the chemical composition of the neoprene seals.

Major points made in the memorandum dated 19 July 2001 are as follows:

1. Nickeldialkyldithiocarbamate is an eye irritant and exposure can produce an adverse reaction when alcohol is simultaneously consumed.

2. IARC and NTP have designated some nickel compounds as potential carcinogens. However, no chronic studies have been conducted on nickeldialkyldithiocarbamate. Therefore, nickeldialkyldithiocarbamate should be regarded as potentially carcinogenic.

3. The primary routes of entry into the body for this compound is inhalation and skin absorption.

4. The median lethal dermal dose in rats is >2 g/kg and would equate to a dermal application of more than 0.39 pounds or 180 grams for a 175 pound person. Median lethal oral doses are >5 g/kg in rats.

5. The median lethal inhalation dose is reported at 0.416 mg/liter. The hazard of the film becoming airborne is low as it tends to stick to the neoprene surface.

6. The amount of [green] film harvested from any one seal amounts to less than 0.01 grams "...thus it is highly unlikely that operators or maintainers would suffer any toxic or even irritating dermal exposure".

7. MSDS-recommended personal protection measures include avoiding personal contact, observing good personal hygiene, and wearing chemical resistant gloves and goggles during handling and NIOSH-certified high efficiency particulate ventilators in the absence of adequate ventilation.

8. The memorandum indicates that in the future, any green film appearing on the seals will be wiped off using a disposable cloth dampened with acetone prior to issue. Seals will be routinely cleaned throughout the flying season and cleaning will occur in well-ventilated area, using chemical resistant gloves, goggles, and NIOSH face mask if area is not well ventilated.

9. Operators and maintainers will be briefed on the importance of avoiding dermal contact and hand-to-mouth oral exposure to the green film.

Surface Concentration Levels of Nickel Found on Hyperstretch Neoprene Wrist and Neck Seals

Surface concentrations of Ni present on 4 wrist and 4 neck seals were determined by Galbraith Laboratories, Inc (Galbraith 2001). Wrist and neck seals with the greatest amount of green surface film were selected from storage for analysis. Ni surface concentration levels were estimated by washing the seals with 150 ml of acetone, evaporating the surface wash, and then measuring the concentration of Ni present in the wash material by NMR spectroscopy. The average concentration of Ni present on the surface of the wrist and neck seals was determined to be 5.33 and 3.59 $\mu g/cm^2$, respectively.

Exposure Assessment of Ni present on the Surface of Hyperstretch Neoprene Wrist and Neck Seals

Lifetime Average Daily Dose (LADD) levels for Ni from dermal contact to Hyperstretch neoprene wrist and neck seals are listed in Table 1. We assumed that exposure to Ni present on the seals by the oral or inhalation routes is not likely and contribute very little to our LADD estimates for Ni.

Dermal LADD estimates for Ni were calculated using worst case, central tendency, and most likely exposure assumptions and average Ni surface concentrations determined by Galbraith Laboratories. For each exposure scenario, LADDs were calculated using the standard LADD equation for the dermal route of exposure USEPA (1997). LADDs for Ni for wrist and neck seals are reported in Table 1. The combined LADD estimates for exposure to 1 neck and 2 wrist seals are reported in Table 2.

Assumptions used for calculating the worst case were an Ni skin penetration factor of 3.5% (Fullerton et al. 1986), a contact frequency of 4 times per day, 365 days a year, and an exposure duration of 30 years (expected maximum career length). Assumptions used in calculation of the central tendency LADD were a Ni skin penetration factor of 3.5% (Fullerton et al. 1986), a contact frequency of 4 times per day, 270 days a year, and an exposure duration of 10 years. The exposure frequency of 270 days a year assumes 5-day workweeks and average employment duration of persons wearing the Multifab suites of 10 years. Assumptions made for calculation of the most likely LADD were a Ni skin penetration factor of 0.23% (Fullerton et al. 1986), a contact frequency of 2 times per day, 10 days a year, for 20, 10, or 5 years. The most likely contact and exposure frequencies were developed through discussions with Ms. Todd. Most likely LADDs were calculated using an exposure duration of 5, 10, and 20 years to model the effect of length of employment on the LADD.

The LADDs in Tables 1 and 2 most likely overestimate Ni exposure levels from wrist and neck seals by the dermal route. Sources of overestimation include exposure frequency, criteria used in selecting seals for chemical analysis, and absorbed dose per event. Nonmilitary personnel are asked to wear the suits during helicopter flights only when the water is below a certain temperature. Therefore, a contact frequency of 10 days per year may be an overestimate. Criteria used for the selection of seals for Ni analysis ensured that samples containing the greatest amount of green film were chosen and the average amount of surface contamination of remaining seals may be significantly less. The fraction of Ni absorbed from dermal contact with Ni is based on the penetration of soluble Ni salts (Fullerton et al. 1986) and probably overestimates the fraction of nickeldialkyldithiocarbamate that penetrates through human skin. Nickeldialkyldithiocarbamate is insoluble in H_2O (Uniroyal 1995) suggesting that very little of the compound would penetrate through human skin.

Toxicological Risk Characterization of Ni present on the Surface of Hyperstretch Neoprene Wrist and Neck Seals

There is no data on the carcinogenicity of nickeldialkyldithiocarbamate (Uniroyal 1995). IARC classifies "nickel compounds" as Group 1 carcinogens[1]; USEPA classifies

[1] IARC definition: *Agent or mixture is carcinogenic to humans. The exposure circumstance entails exposures that are carcinogenic to humans.* This category is used when there is *sufficient evidence* of carcinogenicity in humans. Exceptionally, an agent (mixture) may be placed in this category when evidence of carcinogenicity in humans is less than sufficient but there is *sufficient evidence* of carcinogenicity in experimental animals and strong evidence in exposed humans that the agent (mixture) acts through a relevant mechanism of carcinogenicity.

nickel refinery dusts and nickel subsulfide as Group A carcinogens[2]. Therefore, the default is to consider nickeldialkyldithiocarbamate a carcinogen until data is produced to the contrary.

To estimate the risk of a person developing cancer from exposure to chemicals, a cancer potency factor is multiplied times the estimated LADD for the particular exposure. Cancer potency factors have been developed by the USEPA for many compounds and are specific for oral, inhalation, or dermal routes of exposure. A cancer potency factor for the inhalation of Ni refinery dusts has been developed (IRIS 1991). However, no cancer potency factors have been developed for chronic dermal contact with Ni. Therefore, the risks for cancer corresponding to dermal LADDs in Table 2 could not be calculated.

Evidence for the carciniogenicity of Ni is based on an increased frequency of lung and nasal tumors in animals and humans following inhalation exposure. Two chronic studies did not find evidence of the carcinogenicity of nickel acetate when fed to mice in their drinking water (ATSDR 1993). Although it cannot be ruled out that Ni or nickeldialkyldithiocarbamate may be carcinogenic by the dermal route of exposure, it seems unlikely that dermal exposure to Ni or nickeldialkyldithiocarbamate would increase the incidence of lung and/or nasal tumors in exposed populations. Although there are some exceptions, lung and nasal cancer are almost always specific to inhalation exposures. Inhalation exposure to Ni or nickeldialkyldithiocarbamate from Hyperstretch neoprene wrist and neck seals is not likely to occur accept in cases where the seals are shredded or torn.

There is no information on the noncancer effects of nickeldialkyldithiocarbamate exposure. It has been shown that soluble Ni compounds causes decreased body and organ weights in rats fed Ni in their diets for 2 years. There is no data on the toxic effects of chronic dermal exposure to Ni compounds for humans or laboratory animals.

Reference doses (RfDs) are threshold lifetime daily dose level that is not anticipated to be harmful to humans. RfDs are most often derived by applying safety factors to chronic toxicity threshold data from experiments in animals. RfDs are rarely developed using human toxicity data. USEPA has derived an oral RfD for Ni of 0.02 mg/kg/day. This RfD was derived from the threshold dose level that caused a decrease in body and organ weights in rats fed soluble Ni salts in their diet for 2 years (IRIS 1996).

Comparison of LADD estimates with oral RfD for Ni shows that Central tendency and Most likely exposure scenario LADDs are lower than the RfD (Table 1). The LADD estimate for the Worst case exposure scenario is 50% higher than the oral RfD for Ni (Table 2). This comparison seems to indicate that chronic systemic toxicity due to Ni exposure from neoprene seals is not likely to occur accept when exposure circumstances are similar to those used for estimating Worst case LADDs. Because of its insolubility in water, the dermal transfer rate for nickeldialkyldithiocarbamate across the skin barrier is probably a fraction of the transfer rate for soluble nickel salts. Smaller dermal transfer

[2] USEPA definition: Human carcinogen

rates would result in smaller LADDs for Ni associated with dermal exposure to Hyperstretch neoprene wrist and neck seals.

Conclusions and Recommendations:

- We have consulted with the McCrone Group and agree that the green film is most likely a nickeldialkyldithiocarbamate rubber additive (CAS# 13927-77-0) that is blooming on the surface of seals kept in storage.

- Since there is little useful data on the toxicity or carcinogenicity of nickeldialkyldithiocarbamates, a conservative approach is to assume that nickeldialkyldithiocarbamates have the same toxic properties as soluble nickel compounds.

- Nickel and nickel compounds are classified as human carcinogens (IARC 1990, NTP 1984, IRIS 1991). Epidemiology and experimental studies have shown that Ni dusts and Ni subsulfide cause tumors when exposure is by the inhalation route (IRIS 1991). Tumors were not induced in mice given Ni at high concentrations over a lifetime. Overall, the evidence suggests that Ni is a carcinogen by the inhalation route only, however, we cannot rule out that chronic application of nickeldialkyldithiocarbamate to the surface of the skin induces cancer.

- Our LADD calculations suggest that the average surface concentration of Ni present on Hyperstretch neoprene seals does not pose a significant risk for noncancer toxic effects. This conclusion is based on the small amounts of Ni present on seal surfaces, the insolubility of nickeldialkyldithiocarbamate in water, and the fact that individuals will be wearing these suits infrequently. Our conclusions assume that Ni and nickeldialkyldithiocarbamate produce similar toxic effects at similar dose levels.

- Our LADD calculations assume that the potential for oral and inhalation exposure to Ni from neoprene seals is negligible. It is possible that a person could be exposed to nickeldialkyldithiocarbamate by hand-to-mouth transfer or by inhalation of airborne neoprene seal particles.

- Dermal contact with Ni-containing materials may cause allergic skin sensitization and contact dermatitis in certain individuals (ATSDR 1993). Allergic contact dermatitis is characterized by redness and edema of the skin following chronic dermal contact with Ni and is promoted by friction and sweating (ATSDR 1993). One to 5% of males and 7-14% of females are sensitized to dermal contact with Ni (ATSDR 1993). We did not find any information on the surface concentrations of Ni that can precipitate allergic contact dermatitis reactions.

- Acetone at a concentration of 70-75% should be used to wipe excess nickeldialkyldithiocarbamate from the surface of the neoprene seals at least 10 minutes prior to issue. Seals do not need to be cleaned except when prior to issue. Acetone is a solvent for dissolving rubber and frequent cleaning of the seals with acetone may cause rapid degradation of neoprene rubber over time.

- Persons involved in the cleaning of the neoprene seals should wear a NIOSH-approved respirator with an organic vapor cartridge.

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Table 1: Estimated Lifetime Average Daily Dose (LADD) levels of Ni associated with dermal contact with Hyperstretch neoprene seals

Exposure Scenario	Ni surface concentration (mg/cm^2)	Absorbed dose/event[1]	Contact frequency (events/day)	Exposure frequency (days/year)	Exposure duration (years)	Skin surface (cm^2)[2]	Body weight (kg)[3]	Averaging time (days)[4]	Number of seals on suit	LADD[5] (mg/kg/day)
Neck seal										
Worst case	3.59E-03	100%	4	365	30	5,690	70	25,550	1	5.00E-01
Central tendency	3.59E-03	3.5%	4	270	10	854	71.8	3,650	1	4.42E-03
Most likely	3.59E-03	0.23%	2	10	20	838	71.8	7,300	1	5.28E-06
					10			3,650		5.28E-06
					5			1,825		5.28E-06
Wrist seals										
Worst case	5.33E-03	100%	4	365	30	1980	70	25,550	2	5.17E-01
Central tendency	5.33E-03	3.5%	4	270	10	990	71.8	3,650	2	1.52E-02
Most likely	5.33E-03	0.23%	2	10	20	360	71.8	7,300	2	6.74E-06
	5.33E-03				10			3,650		6.74E-06
	5.33E-03				5			1,825		6.74E-06

[1] Absorbed Ni dose/event for Central tendency and Most likely based on studies by Fullerton et al. (1986)
[2] EPA (1997) Exposure Factors Handbook: Neck seal Worst case is SA for trunk plus neck, Central tendency SA is 15% of SA of Worst case; Wrist seals Worst case is SA for forearms and hands, Central tendency SA is for hands
[3] EPA (1997) Exposure Factors Handbook
[4] Exposure duration times the number of days in a year (365 days)
[5] Lifetime average daily dose of Ni from exposure to 1 neck seal or 2 wrist seals

Table 2: Comparison of LADD estimates for Ni associated with dermal contact with Hyperstretch neoprene seals versus the oral RfD for Ni

Exposure Scenario	$LADD_{total}$[1] (mg/kg/day)	Percent oral RfD for Ni[2]
Worst case	1.02E+00	> 50%
Central tendency	1.96E-02	< 0.9%
Most likely	1.20E-05	< 1,660%

[1] Combined LADD estimate for dermal contact with 1 neck seal and 2 wrist seals
[2] The oral RfD for Ni is 0.02 mg/kg/d (IRIS 1996)

DRAFT MEMORANDUM FOR RECORD

FROM: WENDY L. TODD, 4.6.3.1

SUBJECT: STATUS OF HYPERSTRETCH NEOPRENE (CWU-83/P)

DATE: 19 JULY, 2001

CC: PMA-202

1. PURPOSE. The purpose of this memorandum is to document the shelf life analysis of hyperstretch neoprene used in the CWU-83/P wrist and neck seals. This memorandum also documents identifcation and implications of a fine green film observed on replacement wrist and neck seal stock during government packaging.

2. IDENTIFCATION. Samples of the neoprene with green film were submitted to the NAWCAD Aerospace Materials Division for analysis. Identification was attempted by several methods: two types of spectroscopic analysis, X-ray diffraction, and spectrometry. Scanning electron microscopic imaging showed fine, needle-type crystals growing up from the surface of the rubber, in a sparse field of round amorphous particles. Elemental energy dispersive spectrometry (EDS) analysis determined that the spectra of the needle-like crystals were consistent with nickel and sulfur; the exact chemical compound remained unknown. The spectra of the round particles were consistent with carbon and oxygen, as in a starch. A common starch, talc, is often applied to rubber compounds during manufacturing to facilitate handling, and is benign.

The samples were then sent to the McCrone Group (Chicago , Illinois). These scientists performed and confirmed that spectra of the round particles were consistent with a starch. Repeat EDS detected the presence of carbon in addition to sulfur and nickel. The spectra of the substance closely matched that of nickeldialkyldithiocarbamate. McCrone reports that di-ethyl, dithiocarbamates are frequently added to rubber compounds as anti-oxidant/anti-ozonants. Thus, they conclude that it is highly likely that the green film on the neoprene is nickel-dialkyl-dithiocarbamate.

3. TOXICITY. The Material Data Safety Sheet for a common nickel-dialkyl-dithiocarbamate, Naugard® NBC Uniroyal Chemical Company, (Attachment 1)reports specific hazards as follows:

"Contact with eyes may cause irritation. Exposure can produce an adverse reaction when alcohol is consumed. Some Nickel compounds have been designated as potential carcinogens by IARC and NTP. While no chronic studies have been conducted on this material, this product should be regarded as being potentially carcinogenic "

From the MSDS, primary routes of entry are inhalation and skin absorption. The median lethal dermal dose is >2g/kg in rats. Thus, for every kilogram of body weight, more than 2g of material applied to the skin would be required to be toxic. For a 175 pound man, that would equate to more than 0.39 lb (or 180g). Carefully harvested, the amount of film on even the largest seal amounts to less than 0.01g. Thus, it is highly unlikely that operators or maintainers would suffer any toxic or even irritating dermal exposure. Median lethal oral doses are even higher, at >5g/kg in rats, a more unlikely risk yet for humans. The median lethal inhalation dose, however, is reported at 0.416 mg/liter in rats. which is somewhat more difficult to translate to human terms. The hazard of film becoming airborne is low as the it tends to stick to the neoprene surface. Mild mechanical action (i.e., wiping, scraping) is required to remove the film.

The MSDS recommended engineering controls include: sufficient ventilation to minimize dust exposure; protection of closed handling systems against possible dust exposure, and avoiding dust accumulation on building or equipment surfaces. MSDS recommended personal protection measures include avoiding personal contact, observing good personal hygiene, wearing chemical resistant gloves and goggles during handling, and NIOSH-certified high efficiency particulate respirators in the absence of adequate ventilation.

NAWCAD concludes from the MSDS information that any film shall be wiped off using a disposable cloth dampened with acetone prior to issue. Seals shall routinely cleaned throughout the flying season to remove any freshly bloomed compound. Cleaning shall occur in a well-ventilated area, using chemical resistant gloves, goggles, and NIOSH face mask if area is not well ventilated. Operators and maintainers shall be briefed on the importance of not inadvertently conveying any of the film to the face, especially the mouth. All materials handling information and shall be distributed via NAVAIR 13-1-6.7 and via Interim Rapid Action Change naval message.

4. SHELF LIFE. In the event that the blooming of the nickel compound is evidence of chemical decomposition, thermogravimetric analysis was performed to determine the time to chemical decomposition by measuring the weight loss as a function of temperature at various heating rates. This analysis is in process; however preliminary results indicate that the shelf life is not likely to be affected by the blooming film. A naked sample has yet to lose 1% of its weight after 2 months of high temperature aging, a very encouraging trend. The estimated disposal date shall be included on the item and container label.

5. POC for this issue is Wendy Todd, Code 4631, DSN 342-9224.

REPORT DOCUMENTATION PAGE

Form Approved OMB No. 0704-0188

1. REPORT DATE *(DD-MM-YYYY)*	2. REPORT TYPE	3. DATES COVERED *(From - To)*
12-01-2001	Final	December 2001

4. TITLE AND SUBTITLE
Toxicological Risk Assessment of A Nickel Compound Found on the Surfaces of Replacement Hyperstretch Neoprene (CWU-83/P) Neck and Wrist Seals for a Cold Water Submersion Survival Suit

5a. CONTRACT NUMBER

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Darryl P. Arfsten, Linda V. Kane, Kenneth R. Still

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
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8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)
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10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION/AVAILABILITY STATEMENT

Approved for public release; distribution is unlimited.

13. SUPPLEMENTARY NOTES

14. **ABSTRACT** *(Maximum 200 words)*
Naval Health Research Center/Toxicology was requested to provide comment and endorse an action plan developed by Naval Air Warfare Center Aeronautics Division (NAWCAD) to remove surface nickel from hyperstretch neoprene (CWU-83/P) neck and wrist seals used in cold water submersion survival suits. The nickel compound present on the surface of the seals is most likely nickeldialkyldithiocarbamate which is a common chemical additive used to prevent photoxidation and breakdown of rubber materials. There is no data on the chronic toxicity or carcinogenicity of nickeldialkyldithiocarbamates. The conservative approach for estimating the toxicological risk of nickeldialkyldithiocarbamate exposure to humans is to assume that these compounds have the same toxic properties as soluble nickel compounds. Lifetime average daily dose (LADD) estimates for persons wearing cold water survival suits were calculated using conservative exposure assumptions. Our calculations suggest that the average surface concentrations of Ni present on Hyperstretch neoprene seals do not pose a significant noncancer toxicological risk for humans. It is possible that a person could be exposed to nickeldialkyldithiocarbamate by hand-to-mouth transfer or by inhalation of airborne neoprene seal particles. However, it was assumed that the potential for oral and inhalation exposure to Ni from exposure to neoprene seals is most likely negligible. Dermal contact with Ni-containing materials may cause allergic skin sensitization and contact dermatitis in certain individuals; the surface concentration of Ni that elicits allergic contact dermatitis reactions in humans has not been determined. Acetone at a concentration of 70-75% should be used to wipe excess nickeldialkyldithiocarbamate from the surface of the neoprene seals at least 10 minutes prior to issue. Seals do not need to be cleaned except when prior to issue. Acetone is a solvent for dissolving rubber and frequent cleaning of the seals with acetone may cause rapid degradation of neoprene rubber over time. Persons involved in the cleaning of the neoprene seals should wear a NIOSH-approved respirator with an organic vapor cartridge.

15. SUBJECT TERMS
hyperstretch neoprene, nickel, nickeldialkyldithiocarbamates, dermal contact, lifetime average daily dose (LADD)

16. SECURITY CLASSIFI-CATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
				34	CAPT K. R. Still
a. REPORT	b. ABSTRACT	c. THIS PAGE			19b. TELEPHONE NUMBER *(Include area code)*
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